REMARKS

Claims 1 and 11-13 have been amended herein. Claims 2, 7, 9, 18, and 19 have been canceled. Such cancelation is without prejudice on the merits to further prosecution of these claims in one or more continuing applications. Claim 20, depending from Claim 5, is newly added. Claims 1, 3-6, 7-17, and 20 remain in the application. Favorable reconsideration is respectfully requested.

In claim 1, the surfactant mixture recited as having a hydrophilic-lipophilic balance of from 2 to 5. See page 5, paragraph 2 of the specification for support. In addition, the subject matter of claim 9 (now canceled) has been incorporated into claim 1. That is, claim 1 now recites that the vehicle is an acrylic-based polymer, a cellulose-based polymer or a polyvinyl-based polymer.

New claim 20, depending from claim 5, recites that the mixture is sorbitan sesquioleate. Support for claim 20 can be found in the specification at page 6, lines 1-2.

The registered trademarks in claim 11 have been replaced with the systematic chemical names of the polymers. The systematic chemical names of the different Eudragit-brand polymers can be found in many medical handbooks, such as the "Handbook of Pharmaceutical Excipients", First Edition, edited by Rowe, Sheskey and Owen (2006). The corresponding formulae are also given on the website of EVONIK, the manufacturers of Eudragit-brand polymers, at http://eudragit.evonik.com.

Claim 13 has been amended to insert the word "or" between "bendrofluazide" and "orbudesonide."

Information Disclosure Statement:

The Office indicated that it did not receive copies of the non-patent literature which were cited in the Information Disclosure Statement filed July 20, 2006. Applicants' counsel regrets the omission. Copies of the following documents are submitted herewith:

Jameela S R et al (Vol 52, No. 1-2, March 2, 1998, Pages 17-24)

Mateovic T et al (Vol 14,2003, pages 53-66)

Pradhan, R S et al (Vol 30, No.2, May 1, 1994, pages 143-154)

Insofar as these documents are already listed in the IDS filed July 20, 2006, Applicants submit a second IDS form is not required.

Objection to Claim 7:

The objection to claim 7 has been rendered moot by cancelation of the claim.

The objection to claim 13 has been addressed by appropriate amendment to the claim, as noted above.

Rejection of Claims 11 and 12 under §112, Second Paragraph:

This rejection has been overcome by appropriate amendment to the claims. The various "Eudgragit" trademarks have been replaced by corresponding systematic names for the polymers.

Withdrawal of the rejection is respectfully requested.

Rejection of Claims 1-3, 7-12 and 14-16, and Rejection of Claims 4-6 and 17 over the Combination of Satturwar et al., Kim et al., and Bontemps et al.:

Although these two rejections are stated separately in the Office Action, because they rely upon the same combination of references, they shall be traversed together.

Applicants respectfully traverse these two rejections because the person skilled in the art would not combine these references from the outset. Applicants thus submit that the Office has not established a *prima facie* case of obviousness. Firstly, each reference uses a different process and a different reaction temperature. Satturwar describes a method which uses a high temperature (60 ºC for 15 minutes) in order to remove solvent. In contrast, Kim uses a room temperature method. In contrast to both Saturwar and Kim, Bontemps uses a process which takes place at 0 ºC for three hours.

The Examiner is correct that Kim teaches an emulsification method which uses 2% "Span 80" surfactant. However, the "Span 80" surfactant is not a mixture of surfactants as required by claim 1. Combining Satturwar and Kim with Bontemps does not cure this shortcoming because the teaching of Bontemps is incompatible with the teaching of Satturwar and Kim. There are many reasons for this. For instance, Bontemps forms microparticles from a polylactide polymer. The properties of polylactide polymers are completely different from the "Eudragit"-brand polymers described in Satturwar and Kim. The skilled person in the art recognizes that teachings relating to polylactide polymers cannot be applied to "Eudragit"-brand polymers. Furthermore, Bontemps describes sustained release particles with a release profile extending over a period of

days. This is in contrast to the "Eudragit"-brand particles in the other two references, which have a release profile extending over a period of hours. Specifically, compare Table 2 in Bontemps with Figure 4 in Sattuwar et al. and Figures 4 and 5 in Kim at al. In Bontemps, Table 2 reveals that the average release speed, measured in percentage **per day**, ranged from a low of 7.7% to a high of 11.1%. Thus, Bontemps fastest release formulation would extend over a period of 9 days (i.e., **216 hours**). In contrast, Satturwar's formulations are completely spent between about 3 hours and less than 7 hours. See Fig. 4 of Satturwar, age page 412 of the reference. Similarly, Kim's formulations are about 40% to 80% spent after only 120 **minutes**, and about 60% to 90% spent after 300 **minutes**. See Figs. 3-5 of Kim et al. Moreover, the microspheres described in Bontemps are designed for injection into the body (parenteral administration). In contrast, the "Eudragit"-brand particles in the other two references are intended to be administered orally.

Additionally, it is clear that the particle diameters in Satturwar et al. and Kim et al. are completely different to those in Bontemps at al. As can be seen from Table 1 in Bontemps et al., the median particle diameter will not be of "up to 100 microns" (*i.e.*, no larger than 100 microns, as required by present claim 1), but will far exceed this. The majority of the particles in Table 1 of Bontemps all have a diameter greater than 100 microns. The fraction of particles used in Bontemps et al. includes particles having a diameter between 160 and 200 microns. See Bontemps at column 5, lines 45-47). The particles prepared in Satturwar have a median diameter of less than 100 μm (see Table 1 of Satturwar). The same is true for Kim (see Table 2 of the reference).

The preferred surfactant for use in the present invention is sorbitan sesquioleate (see Claim 20). Although sorbitan sesquioleate is mentioned in Bontemps at column 5, line 28, the use of this surfactant is by no means preferred in this reference. For instance, it is stated in column 4, lines 21-22 of Bontemps that particularly suitable surface active agents are sorbitan esters, particularly sorbitan monoleates. Accordingly, the use of a mixture of surfactants with an HLB value of from 2 to 5 (as required by claim I of the present application) is by no means obvious over Bontemps at al.

Rejection of Claims 13 over the Combination of Satturwar et al., Kim et al., Bontemps et al. and Hersh:

The teachings of Satturwar et al., Kim et al., and Bontemps et al. are discussed in the preceding section of this response. Those remarks are incorporated herein by reference.

Note that the Hersh reference is cited solely for its description of prednisone. See page 10, third paragraph of the office action. Applicants readily acknowledge that prednisone is a well known anti-inflammatory agent. (Prednisone has been available commercially in the United States since the mid-1960's.) However, Hersh adds nothing to the disclosures of the other three documents. In short, the three-way combination of Satturwar et al., Kim et al., and Bontemps et al. does not render obvious claim 1 (as argued above). The Hersh reference does not add anything of further relevance with respect to claim 1. Thus, the full four-way combination of references does not render obvious claim 1. Claim 13 depends from claim 1, and thus is also unobvious in view of the full four-way combination of references.

Applicants therefore submit that this rejection is untenable. Withdrawal of the rejection is respectfully requested.

Respectfully submitted,

/Jos. T. Leone/

Joseph T. Leone, Reg. No. 37,170
DeWitt Ross & Stevens S.C.
2 East Mifflin Street, Suite 600
Madison, WI 53703-2865
Fax: 608-252-9243
Ph. 608-255-8891